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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/466,554	06/06/1995	PETER A. SEUBERT	15270-002120	3168

20350 7590 08/16/2004

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/466,554	SEUBERT ET AL.	
	Examiner	Art Unit	
	Patricia A. Duffy	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-46,48 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-46, 48, 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1995, 2001, 2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 27, 2004 has been entered.

The amendment and response filed May 27, 2004 have been entered into the record. Applicants statements of the pending and canceled claims are inconsistent with the actual amendment submitted. Therefore, the actual amendment controls. Claims 42-46, 48 and 51-54 are pending and under examination.

Priority

Applicant's are requested to update the status of any applications for which they claim priority.

Information Disclosure Statement

The information disclosure statements filed 1995, 2001 and 2002 have been considered. Initialed copies are enclosed.

Double Patenting

Claims 42-44, 48 and 51-54 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all the allowed claims of U.S. Patent No. 6,284,221 in view of Viego Pelfrey et al (of Record) and Suzuki et al (of record).

Viego Pelfrey et al teach that there are soluble forms of Aβ (x- ≥ 41) and Aβ(1-42) are specifically present in the CSF of diseased Alzheimer's individuals.

Suzuki et al teach a sandwich enzyme linked immunosorbent assay which measures Aβ(1-42) in a fluid sample using the combination of the monoclonal antibody BAN50, which specifically binds Aβ(1-16) and the monoclonal antibody BC-05 which was raised to Aβ(33-43) (see pages 1337-1338). Suzuki et al teach that the assay was specific for Aβ(1-42) and does not detect Aβ(1-40) and thus innately measures Aβ(x ≥ 41).

It would have been *prima facie* obvious to one of ordinary skill in the art to modify the assay of the '221 patent by measuring the species of soluble Aβ(x- ≥ 41) by means of the assay of Suzuki et al because Viego-Pelfrey et al teach that Aβ(1-42) is a soluble species of Aβ present in fluid samples of disease individuals.

Applicants' arguments have been carefully considered but are not persuasive. The claims are drawn to screening for the ability to alter the amount of an Aβ(x- ≥ 41) in a CSF sample. The patent is drawn to screening for Aβ production inhibitors (i.e. the instantly claimed altering the amount) in CSF (see Patented claim 5). Further, the Patented claims indicate that the soulble Aβ peptide is measured and the Aβ is intact. Viego-Pelfrey is cited to teach that Aβ (x- ≥ 41) is present in the CSF and is "soluble". As such, measurement of the instantly claimed soluble species in CSF using non-cross reactive antibodies of Suzuki et al is in fact obvious.

Claim Rejections - 35 USC § 112

Claims 45 and 46 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Upon reconsideration of the record the enablement rejection as applied in the office action mailed 3-20-01 to use of non-human transgenic animals including rodents having an expression cassette that drives the expression of a sequence which encodes the Swedish mutation of an APP gene is reinstated herein. It is noted that while the co-pending patent referenced in the specification is drawn to rodents, the claims that use the transgenic rodents are not commensurate with the language of the allowed claims. Further, the patent is not enabled for the scope of non-human transgenic animals for reasons made of record therein.

Claims 48 and 52-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

While the specification provides support for the concept of the use of antibodies specific for Aβ(x- ≥ 41) that do not cross react with Aβ(≤ 40) the specification does not support at page 7, the concept of antibodies specific for Aβ(x- 42), Aβ(x- ≥ 42) or Aβ(x- ≥ 43). The specification fails to support the concept at page 17. The specification teaches at page 17, that the antibodies that are raised against amino acids 33-43 of Aβ that does not cross react with of Aβ(1-40) will bind Aβ(1-42). It may also bind to Aβ(x-41) and Aβ(x-43). The recitation of the positive does not support the now claimed negative, nor does it support recitation of antibodies that are "specific for" a particular species. This passage does not support "≥" a particular residue. There is no conception of end-specific species specific antibodies in the specification as filed. The conception is for an antibody that discriminates between those species of soluble Aβ ≤ 40 and the

amyloidogenic species x-41, x-42 and x-43. What is lacking is conception of specificity and non-cross reactivity for the individual amyloidogenic species or end-specific antibodies that do not cross-react.

Claims 48 and 51-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification lacks written description support for antibodies with the instantly claimed binding properties. The claims are drawn to antibodies that "specifically bind" a particular specie of soluble Aβ but do not bind Aβ $\leq$ 40. The specification does not teach, nor does it provide a written description of any antibody that meets the non-cross reactive requirement and is specific for the end of the claimed soluble Aβ as recited in these claims. The cross-reactive antibody made in the specification has not been characterized with respect to its end-specificity. The specification fails to describe the genus and species of specific antibodies now claimed.

Claim 43-46 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 43-46 and 48, the claims are confusing because they have two recitation of the word "claim" and it is unclear if Applicants intend this to be a multiple dependent claim. Applicants should remove the recitation of duplicative word or provide appropriate amendment to insert the desired alternative.

Claim 45 is indefinite from the use of the acronym APP. While acronyms are permissible in patent claims, the acronym must be fully spelled out followed by its abbreviation.

Status of the Claims

All claims stand rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 571-272-0855. The examiner can normally be reached on M-F 6:30 am - 3:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Patricia A. Duffy, Ph.D.

Primary Examiner

Art Unit 1645